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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/986,509

11/09/2001

Graham E. Kelly

7579.0006-01000

5532

500 7590 04/16/2008

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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/986,509	Applicant(s) KELLY, GRAHAM E.	
	Examiner KONATA M. GEORGE	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-86 is/are pending in the application.
- 4a) Of the above claim(s) 33-72 and 79-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 33-86 are pending in this application.

Request for Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 1, 2008 has been entered.

Action Summary

Claims 33-72 and 81-86 remain withdrawn.

The rejection of claims 73-78 under 35 U.S.C. 103(a) as being unpatentable over WO 93/23069 in view of Guggolz et al. is hereby withdrawn in view of applicant arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/23069.

Applicant claims a composition comprising an effective amount of formononetin and biochanin A.

Determination of the scope and content of the prior art

(MPEP §2141.01)

WO '069 teaches a composition comprising two or more components including formononetin, biochanin A, genistein, daidzein and/or their glycosides (claim 1, page 23). Leguminous plants are specified (page 10, last paragraph).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

WO '069 does not disclose that the level of biochanin A is less than about 10% w/w of the isoflavone content.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

The instant invention is directed towards a composition comprising an effective amount of formononetin and biochanin A. As mentioned above, WO '069 discloses the claimed invention comprising a composition containing effective amount of formononetin and biochanin A. With respect to the level of the isoflavone content, it is the position of the examiner that this level is inherent in biochanin A compounds. With respect to the intended use in a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. *In re Maeder et al.* 337 F2d 875, 143 USPQ 248 (CCPA 1964).

The provisional rejection of claims 73-78 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending application 10/611,087 in view of WO 93/23069 and Guggolz et al is being maintained for the reasons stated in the office action dated October 2, 2007.

Response to Arguments

Applicant's arguments filed April 1, 2008 have been fully considered but they are not persuasive.

Applicants argue that it would not have been obvious to modulate the ratios of the formonoectin and biochanin A. The examiner agrees, however, when one looks at

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the claims of the instant invention, one sees that it is drawn to a composition comprising an effective amount of formononetin and biochanin A. Claim 1 of the copending application is also directed to a composition comprising formononetin and biochanin A and/or their glycosides. Since both of the claims read on compositions that are similar, a double patenting rejection is proper and is thus maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants use the phrase “less than about” in the claims when describing the wt% of genistein if present. It is unclear to the examiner if it is “less than” or “about” are the intended values.

Conclusion

Claims 73-78 remain rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-

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272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Art Unit 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616